The following corrections or additions to the January 1999 list were made in April 1999

New Approvals

ANADA Number: 200-253

Pioneer Product:	108-901
Trade Name:	ProsaMate™ Sterile Solution
Ingredients:	Dinoprost tromethamine
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	02/12/99
Status:	Prescription only
Route:	Intramuscular
Species:	Non lactatating cattle, swine, mares
Drug Form:	Solution
Concentration:	5 mg/mL
Indications:	For estrus synchronization, treatment of unobserved (silent) estrus and pyometra (chronic endometritis) in cattle; for abortion of feedlot and other non-lactating cattle; for parturition in swine; and for controlling the timing of estrus in estrous cycling mares and clinically anestrous mares that have a corpus luteum.

21CFR 522.690

ANADA Number: 200-258

Pioneer Product:	046-285
Trade Name:	Sulfadimethoxine Soluble Powder
Ingredients:	Sulfadimethoxine sodium
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	03/04/99
Status:	Over-the-counter
Route:	Oral
Species:	Broiler and replacement chickens; turkeys for meat; beef cattle, dairy heifers and dairy calves
Drug Form:	Powder
Concentration:	94.6 g sulfadimethoxine sodium per 107 g packet
Indications:	**Chickens**: For the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza. **Turkeys**: For the treatment of disease outbreaks of coccidiosis and fowl cholera. **Cattle:** For the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella spp.* sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Sphaerophorus necrophorus* sensitive to sulfadimethoxine.
Tolerance:	21CFR 556.640: 0.1 ppm (negligible residue) in uncooked edible tissues of cattle. 0.01 ppm (negligible residue) in milk.
Withdrawal:	Chickens and turkeys: 5 days Cattle: 7 days

21CFR 520.2220(a)

ANADA Number: 200-232

Pioneer Product:	113-232
Trade Name:	Geomycin 200
Ingredients:	Oxytetracycline
Sponsor:	Pliva, d.d.
Approval Date:	02/12/99
Status:	Over-the-counter
Route:	Intramuscular in swine, intramuscular or intravenous in cattle
Species:	Beef cattle, non-lactating dairy cattle, and swine
Drug Form:	Liquid (solution)
Concentration:	200 mg/mL
Indications:	**Cattle**: For the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Hemophilus* spp.; infectious bovine *keratoconjunctivitis* (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum;* bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; and wound infection and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline. **Swine**: For the treatment of the bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused *by Leptospira pomona.* In sows as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli.*
Tolerance:	21CFR 556.500: Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of cattle, beef calves, nonlactating dairy cattle, dairy calves, swine, sheep, chickens, turkeys, catfish, lobsters, and salmonids, as follows: 2 parts per million (ppm) in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.
Withdrawal:	28 days

21CFR 522.1660 and 510.600

NADA Number: 141-123

Trade Name:	GastroGard™	
Ingredients:	Omeprazole	
Sponsor:	Merial Ltd.	
Approval Date:	03/16/99	
Status:	Prescription only	
Route:	Oral	
Species:	Horses and foals 4 weeks of age and older	
Drug Form:	Paste	
Concentration:	2.28 g/syringe (37% w/w)	
Indications:	For the treatment and prevention of recurrence of gastric ulcers in horses and foals 4 weeks of age and older.	
Patent No.:	4,255,432	Expiration date: 04/05/2001
	5,708,017	Expiration date: 04/04/2015
Exclusivity:	5 years	

21CFR 520.1615

NADA Number: 141-112

Trade Name:	Maxiban®, BMD®, 3-Nitro®
Ingredients:	Narasin/Nicarbazin (in a 1:1 fixed dose combination), bacitracin methylene disalicylate, roxarsone
Sponsor:	Alpharma, Inc.
Approval Date:	03/04/99
Status:	Over-the-counter
Route:	Oral
Species:	Broiler chickens
Drug Form:	Type A Medicated Articles to make Type C medicated feeds
Concentration:	Narasin/Nicarbazin: 27 to 45 g/lb Type A Medicated Article Bacitracin methylene disalicylate: 10, 25, 30, 40, 50, 60, or 75 g/lb Type A Medicated Article Roxarsone: 45.4, 90, or 227 g/lb Type A Medicated Article
Indications:	For prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin; for increased rate of weight gain; improved feed efficiency, and improved pigmentation in broiler chickens.
Tolerance:	21 CFR 556.60: Arsenic residues (from roxarsone): 0.5 ppm in uncooked edible muscle and 2 ppm in uncooked edible by-products of chickens. 21 CFR 556.70: Bacitracin: 0.5 ppm negligible residue in uncooked edible tissues of chickens. 21 CFR 556.445: Nicarbazin: 4 ppm in uncooked chicken muscle, live, skin, and kidney 21 CFR 556.428: Narasin: A tolerance for residues in chickens is not needed. The safe concentrations for total narasin residues in uncooked edible chicken tissues are: 0.6 ppm muscle; 1.8 ppm in liver; 1.2 ppm in skin with adhering fat.
Withdrawal:	5 days

21CFR 558.76, 558.363, 558.366, and 558.530

NADA Number: 141-113

Trade Name:	Maxiban®, 3-Nitro®
Ingredients:	Narasin/Nicarbazin (in a 1:1 fixed dose combination), roxarsone
Sponsor:	Elanco Animal Health, a Division of Eli Lilly and Co.
Approval Date:	03/04/99
Status:	Over-the-counter
Route:	Oral
Species:	Broiler chickens
Drug Form:	Type A Medicated Articles to make Type C medicated feeds
Concentration:	Narasin/Nicarbazin: 36 g/lb Type A Medicated Article Roxarsone: 45.4, 90, or 227 g/lb Type A Medicated Article
Indications:	For prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*; for increased rate of weight gain; improved feed efficiency, and improved pigmentation in broiler chickens.
Tolerance:	21 CFR 556.60: Arsenic residues (from roxarsone): 0.5 ppm in uncooked edible muscle and 2 ppm in uncooked edible by-products of chickens. 21 CFR 556.445: Nicarbazin: 4 ppm in uncooked chicken muscle, live, skin, and kidney. 21 CFR 556.428: Narasin: A tolerance for residues in chickens is not needed. The safe concentrations for total narasin residues in uncooked edible chicken tissues are: 0.6 ppm muscle; 1.8 ppm in liver; 1.2 ppm in skin with adhering fat.
Withdrawal:	5 days

21CFR 558.363, 558.366, and 558.530

Supplemental Approvals

NADA Number: 048-271

Trade Name:	Task® Tabs
Ingredients:	Dichlorvos
Sponsor:	Boehringer Ingelheim Vetmedica, Inc.
Approval Date:	03/04/99
Status:	Prescription only
Route:	Oral
Species:	Dogs, puppies, cats, and kittens
Drug Form:	Tablet
Concentration:	10, 25, 50 and 100 mg/tablet
Indications:	**Cats**: For the removal and control of roundworms (*Toxocara cati, Toxascaris leonina)* and hookworms (*Ancylostoma tubaeforme, Uncinaria stenocephala)* occurring in the intestinal tract. **Dogs:** :For the removal and control of roundworms (*Toxocara canis, Toxascaris leonina)* and hookworms (*Ancylostoma caninum, Uncinaria stenocephala)* occurring in the intestinal tract

This supplemental application provides for the use in kittens not less than three months of age, for the use in adult dogs, and the addition of the 50 and 100 mg tablet sizes. Also, the list of sponsors is amended to reflect the sponsor's current zip code (64506-2002).

21CFR 520.600 and 510.600

NADA Number: 141-043

Trade Name:	Synovex® Plus
Ingredients:	Trenbolone acetate, estradiol benzoate
Sponsor:	Fort Dodge Animal Health Division of American Home Products
Approval Date:	03/16/99
Status:	Over-the-counter
Route:	Subcutaneous
Species:	Cattle
Drug Form:	Implant
Concentration:	200 mg trenbolone acetate and 28 mg estradiol benzoate/implant
Indications:	For increased rate of weight gain and improved feed efficiency in steers and for increased rate of weight gain in heifers fed in confinement for slaughter.
Tolerance:	21CFR 556.240 Estradiol and related esters: The tolerance in uncooked edible tissues of heifers, steers, and calves are: 120 ppt for muscle, 480 ppt for fat, 360 ppt for kidney, and 240 ppt for liver. Trenbolone: A tolerance is not needed. The Acceptable Daily Intake (ADI) for total residues of trenbolone is 0.4 mcg/kg of body weight/day.
Withdrawal:	Zero days
Exclusivity:	3 years

This supplemental application provides for implantation in steers fed in confinement for slaughter for increased rate of weight gain and the establishment of an ADI for trenbolone.

21CFR 522.2478 and 556.739

NADA Number: 010-005

Trade Name:	Wazine®, Pig Wormer
Ingredients:	Piperazine hydrochloride, dipiperazine sulfate
Sponsor:	Fleming Laboratories, Inc.
Approval Date:	03/23/99
Status:	Over-the-counter
Route:	Oral
Species:	Chickens not laying eggs for human consumption, turkeys, swine
Drug Form:	Powder and liquid
Concentration:	17,34, or 230 grams/pound or 17,34, or 230 grams / 100 ml
Indications:	For the removal of large roundworms (*Ascaridia* spp.) from chickens and turkeys; and large roundworms (*Ascaris suum*) and nodular worms (*Oesophagostomum* spp.) from swine.
Tolerance:	21CFR 556.513: A tolerance of 0.1 ppm is established for all tissues of poultry and swine.
Withdrawal:	Chickens and turkeys - 14 days Swine - 21 days

This supplemental application provides for DESI finalization and establishes a tolerance for piperazine base.

21CFR 520.1807 and 556.513

New Sponsor

Pliva, d.d.
Ulica grada Vukovara 49
10000 Zareb, Croatia
Drug labeler code: 011722

Suitability Petition Action

Number:	**99P-0923/CP1**
Sponsor:	Pharmaderm, Veterinary Division of Altana, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug miconazole nitrate which differs from the pioneer product, Conofite® Cream 2%, Schering-Plough Animal Health Corporation, NADA 095-183, by the following characteristics: The generic will provide for a product containing 20 mg miconazole nitrate per g of cream as opposed to the pioneer product which contains 23 mg miconazole nitrate per g of cream.
Action:	Filed on 04/02/99